REMARKS

This Amendment is submitted in reply to the final Office Action mailed on April 17, 2009. A Petition to Revive the application is submitted herewith this Amendment. The Director is authorized to charge $1620.00 for the Petition to Revive and any additional fees that may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 3712036-00694 on the account statement.

Claims 1-13 and 15-20 are pending in this application. Claims 1-10, 12-13, 15 and 19-20 were previously withdrawn. Claim 14 was previously canceled. In the Office Action, Claims 17-18 are rejected under 35 U.S.C. § 112. Claims 11 and 17-18 are rejected under 35 U.S.C. §102. In response, Claims 11 and 17-18 have been amended. The amendments do not add new matter and are supported in the specification at, for example, page 6, lines 1-6. In view of the amendments and/or for the reasons set forth below, Applicants respectfully submit that the rejections should be withdrawn.

In the Office Action, Claims 17-18 are rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, with respect to Claim 17, the Patent Office asserts that neither the claims nor the specification provides any means of accomplishing the "step" of " ensuring an optimal barrier function in infants." The Patent Office further states that "the use of the word 'an' implies there are multiple barrier functions and that only one needs to be optimized." See, Office Action, page 7, lines 10-21. Regarding Claim 18, the Patent Office alleges that neither the claims nor the specification provide any means of accomplishing the "step" of "reducing the risk of developing allergy and infection." See, Office Action, page 8, lines 14-16.

In contrast, however, Applicants respectfully submit that the specification describes how, during postnatal development, a newborn intestine experiences a process of maturation that ends by the establishment of a functional barrier to macromolecules and pathogenic bacteria. This phenomenon is called gut closure and appears to be affected by the newborn's diet. Hence, different studies with infants (JPGN, 1995, 21: 383-6) and animal models (Pediatr. Res., 1990, 28: 31-7) show that the maturation of the barrier is faster in breast-fed than in formula-fed newborns. This could explain the higher prevalence of allergy and infection in infants fed

formula than in those fed with mother milk. See, specification, page 1, lines 13-19. Further, the specification also clearly demonstrates that gut barrier function or gastrointestinal health in infants may be improved by providing specific bioactive ingredients combined with microorganisms that are able to deliver at least one of the ingredients all along the intestine. See, specification, page 3, lines 2-5. Moreover, the specification also clearly demonstrates, via Example 1, that rats who consumed compositions of the present invention were found to have restored intestinal permeability to normal levels after maternal separation, which increased the intestinal permeability to proteins and other macromolecules. See, specification, page 15, lines 2-4. This Example illustrates how the use of the compositions of the present invention work to ensure an optimal barrier function in infants (*e.g.*, rat pups). See, specification, Example 1.

Accordingly, in contrast to the Patent Office's assertion that Applicants have failed to address the rejection, Applicants respectfully submit that the specification is replete with disclosure indicating that administration of the compositions both "ensures" and "reduces," as required, in part, by Claims 17 and 18. Further, Applicants also note that the word "an" has been deleted from currently amended Claim 17.

Therefore, in view of the amendments and/or for at least the reasons set forth above, Applicants respectfully submit that the skilled artisan would immediately understand the scope of amended Claims 17-18 when read in view of the specification. Based on at least these noted reasons, Applicants believe that Claims 17-18 fully comply with the requirements of 35 U.S.C. §112, second paragraph.

Accordingly, Applicants respectfully request that the rejection of Claims 17-18 under 35 U.S.C. §112, second paragraph be reconsidered and withdrawn.

In the Office Action, Claims 11 and 17-18 are rejected under 35 U.S.C. § 102(b) as being anticipated by WO 01/64225 to Haschke et al. ("*Haschke*") and by WO 03/041512 to Giffard et al. ("*Giffard*"). Applicants respectfully submit that the cited references are deficient with respect to the present claims.

Currently amended independent Claim 11 recites, in part, a method for inducing a pattern of gut barrier maturation comprising the steps of administering a combination of a least one substance selected from the group consisting of fats, non-digestible oligosaccharides and combinations thereof, and at least one microorganism, to an infant, wherein the combination

comprises a polyamide or a polyamide precursor selected from the group consisting of spermidine, spermine, putrescine, cadaverine, ornithin, arginine and combinations thereof. The amendment does not add new matter. The amendment is supported in the specification at, for example, page 6, lines 1-6. During postnatal development, a newborn intestine experiences a process of maturation that ends by the establishment of a functional barrier to macromolecules and pathogenic bacteria (*i.e.*, gut closure). Different studies with infants and animal models show that the maturation of the barrier is faster in breast-fed than in formula-fed newborns, and could aid in explaining the higher prevalence of allergy and infection in infants fed formula than in those fed with mother milk. See, specification, page 1, lines 13-19.

An impressive number of different mechanisms integrate this barrier, mechanisms that act synergistically to protect the host from the luminal aggressions. The first barrier consists on the intestinal epithelium, a continuous monolayer of columnar epithelial cells sealed together by protein complexes, such as the tight junctions. The second is a non-specific barrier composed by mechanisms that protect the mucosal surface as saliva, gastric acidity, mucus layer, proteolytic digestion, alkaline intestinal pH, unstirred layer and intestinal peristalsis. The gut immune system (GALT) is able to respond selectively and specifically to the foreign molecules and pathogen microorganisms. Finally, and not less important, intestinal flora directly and indirectly protect against host invasion by pathogens and macromolecules with antigenic properties. See, specification, page 2, line 21-page 3, line 4.

In accordance with the present claims, Applicants have surprisingly found that gut barrier function or gastrointestinal health in infants may be improved by providing specific bioactive ingredients combined with microorganisms that are able to deliver at least one of the ingredients all along the intestine. See, specification, page 3, lines 2-5. The microorganisms of the present claims, which differ in their ability to survive in the different parts of the gastro-intestinal tract, can be incorporated into a cocktail. Thus, the bioactive ingredients can be added to the microorganism cocktail in order to reinforce their effects by stimulating the maturation of barrier mechanisms different to those stimulated by the microorganisms. See, specification, page 3, lines 11-17. The microorganism of the present invention are designed to release the beneficial substance(s) at a certain desired location of the gut and may be administered to a recipient, whereupon they will lyse at the respective location in the gut depending on the sort of

pretreatment undergone by the microorganism. See, specification, page 7, lines 11-28. The polyamines and/or polyamine precursors of currently amended Claim 11 also provide the advantage of substances that have the potential to favor intestinal cell differentiation. In contrast, Applicants respectfully submit that the cited references fail to disclose each and every limitation of the present claims.

For example, both *Haschke* and *Giffard* fail to disclose or suggest administering a composition comprising a least one substance selected from the group consisting of fats, non-digestible oligosaccharides and combinations thereof, and at least one microorganism, to an infant, wherein the combination comprises a polyamide or a polyamide precursor selected from the group consisting of spermidine, spermine, putrescine, cadaverine, ornithin, arginine and combinations thereof as is required, in part, by currently amended independent Claim 11.

Instead, *Haschke* is entirely directed toward a carbohydrate formulation, and method for administering same, for enhancing an immune response. The carbohydrate formulation includes, primarily, an effective amount of a prebiotic. See, *Hascke*, Abstract. Similarly, *Giffard* is entirely directed toward a foodstuff which comprises colostrum as a primary ingredient. The colostrums may be bovine, ovine or caprine. See, *Giffard*, Abstract, Claim 5. However, at no place in the disclosures do either *Haschke* or *Giffard* even suggest the use of a polyamide or a polyamide precursor, let alone a polyamide or a polyamide precursor selected from the group consisting of spermidine, spermine, putrescine, cadaverine, ornithin, arginine and combinations thereof as is required, in part, by currently amended independent Claim 11. As such, Applicants respectfully submit that *Haschke* and *Giffard* fail to disclose or suggest each and every element of the present claims.

Moreover, anticipation is a factual determination that "requires the presence in a single prior art disclosure of each and every element of a claimed invention." *Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744, 747 (Fed. Cir. 1987) (emphasis added). Federal Circuit decisions have repeatedly emphasized the notion that anticipation cannot be found where less than all elements of a claimed invention are set forth in a reference. See, *e.g.*, *Transclean Corp. v. Bridgewood Services, Inc.*, 290 F.3d 1364, 1370 (Fed. Cir. 2002). As such, a reference must clearly disclose each and every limitation of the claimed invention before anticipation may be

found. For at least these reasons, Applicants respectfully submit that the cited references fail to anticipate the presently claimed subject matter.

Accordingly, Applicants respectfully request that the rejection of Claims 11 and 17-18 under 35 U.S.C. §102 be reconsidered and withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same. In the event there remains any impediment to allowance of the claims which could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

K&L GATES LLP

BY 

Robert M. Barrett
Reg. No. 30,142
Customer No.: 29157
Phone No. 312-807-4204

Dated: October 27, 2009